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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,966	08/05/2003	Scott D. Kuduk	21109	6942

210 7590 07/29/2004

MERCK AND CO INC  
P O BOX 2000  
RAHWAY, NJ 070650907

EXAMINER
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MORRIS, PATRICIA L

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/634,966

Applicant(s)

KUDUK ET AL.

Examiner

Patricia L. Morris

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Election/Restriction*

The variations in X and Y produce patentably distinct compounds capable of independent use.

This application has been found to contain more than one invention. Therefore, restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. The instances wherein X and Y are each CH classified in classes 540, 544 and 546, various subclasses.
- II. The instances wherein X is CH and Y is N, classified in classes 540, 544 and 546, various subclasses.
- III. The instances wherein X is N and Y is CH , classified in classes 540, 544 and 546, various subclasses.
- IV. Claims 34-39, drawn to multiple uses, classified in classes 514, various subclasses.

These inventions are distinct, each from the other because of the following reasons:

These distinct inventions have acquired separate status in the art, will support separate patents, and will require different fields of search for the respective inventions. Accordingly, restriction for examination purposes as indicated is considered proper; 35 U.S.C. 121; 37 CFR 1.141; 37 CFR 1.142.

Inventions I-III are drawn to patentably distinct compounds.

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"A Markush-type claim is directed to "independent and distinct inventions", if two or more of its members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s)". In re Weber, 198 USPQ 330, footnote 3.

A reference to a thiazole here would not be a reference to a pyridine. When one writes out the entire compound, as a whole, one arrives at patentably distinct heterocyclic compounds, along the lines indicated in the Groups of the first page of this action. Distinct, independent, heterocyclic nuclei.

Independent means the compound is capable of being utilized alone, not in combination with other compounds listed in the Markush expression; MPEP 802.01.

If the members are so diverse that they will support separate patents, *i.e.*, a reference for one would not constitute a reference for the other, then restriction is considered proper. MPEP 2173.05(h).

Inventions I-III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products as claimed can be used in materially different processes as evidenced by applicants' own claims and specification.

In the event of an election of either Groups I, II, III, or IV, applicants are required to elect a single disclosed species representative of the claimed invention since the variations in R6a – R6c, etc., encompass all heterocyclic chemistry classified in classes 540, 544 and 546, various

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subclasses. The staggering arrangement of possibilities does not permit classification of the claimed subject matter. Each heterocycle represents an independent and patentably distinct invention.

In the event of an election of Group IV, applicants are also required to elect a single disclosed method of use, *i.e.*, a single disclosed disease.

Should applicant(s) traverse on the ground that the species inventions identified are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the above identified species inventions to be obvious variants, or clearly admit on the record that this is the case. In either instance, of traverse, if the examiner finds one of the inventions in the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

It is too burdensome for the examiner to search all of the previously noted searches in their respective, completely divergent, areas for the non-elected subject matter, as well, in the limited time provided to search one invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claims 1-33 will be examined to the extent readable on the elected compounds.

In, In re Weber, 198 USPQ 332, In re Hengehold, 169 USPQ 473, was noted for the proposition that as long as applicants have maintained the right (as they do here) to file the non-elected subject matter in divisional applications, then restriction is proper, as to that point.

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Applicant may file the divisional subject matter noted in divisional applications. If applicant wishes a generic expression of the elected invention the claims here need be amended to reflect that election.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

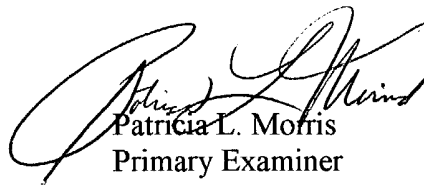
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patricia L. Morris  
Primary Examiner  
Art Unit 1625

plm

July 28, 2004